

composition as those of similar articles involved in the case reported in notices of judgment on drugs and devices, No. 908.

The *System* was alleged to be misbranded in the following manner: Section 502 (a), certain statements in the labeling, including those in accompanying booklets entitled "Directions for Use of Bullock's System" and "Fight Infection with Bullock's System," and in an accompanying folder entitled "Infectious Catarrh Symptoms," were false and misleading since they represented and suggested that the *System* would constitute an effective treatment for acute or chronic sinus trouble, hay fever, nasal catarrh, nasal ailments, infectious catarrh, abscesses and infected teeth, throat and tonsil infections, bronchitis, mastoid trouble, asthma, colitis, ulcers and catarrh of the stomach, tumors, rheumatism, arthritis, blindness, and deafness. The *System* did not constitute an effective treatment for the conditions named. Further misbranding, Section 502 (j), the *System* would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling since it was intended for use in the irrigation of the nasal passages, whereas such irrigation is always accompanied by danger to the health of users by loosening the infected material from the nasal walls and spreading the infection to the opposite nasal passage, to the nasal sinuses, or to the ears.

It was also alleged in the complaint that, previous to the incorporation of Bullock's Laboratories, Inc., the business of preparing and distributing the *System* had been carried on by Henry Spangler as an individual trading under the name of National Laboratories, Inc.; that, while so operating, criminal proceedings had been instituted against Henry Spangler (as reported in notices of judgment on drugs and devices, No. 908), resulting in a sentence of 180 days in jail, which sentence was suspended on condition that he was not then selling and would not again engage in the sale of the *System*; and that, thereafter, Henry Spangler was instrumental in securing, for the purpose of preparing and distributing the *System*, the formation of the corporation known as Bullock's Laboratories, Inc.

PRAYER OF COMPLAINT: That a preliminary injunction issue, restraining the defendants from commission of the acts complained of; and that, after due proceedings, the preliminary injunction be made permanent.

DISPOSITION: On March 13, 1945, the corporation and Theodore T. Golden and Henry Spangler having entered their appearances, and the other defendants having failed to appear, a preliminary injunction was entered, restraining all defendants from shipping any misbranded drugs and devices, and particularly the so-called "Bullock's System," in interstate commerce for the period ending on April 16, 1945. On the latter date, the defendants having failed to answer or otherwise plead to the complaint, a decree was entered directing that the preliminary injunction be made permanent.

1552. Adulteration and misbranding of Interferin. U. S. v. Don C. Keefer (Keefer Laboratories). Plea of nolo contendere. Sentence of 1 year in jail. (F. D. C. No. 7241. Sample Nos. 14766-E, 86683-E.)

INFORMATION FILED: October 25, 1944, Northern District of Illinois, against Don C. Keefer, trading as the Keefer Laboratories, Chicago, Ill.

ALLEGED SHIPMENT: On or about November 3, 1941, and March 19, 1942, from the State of Illinois into the States of Pennsylvania and Wisconsin.

NATURE OF CHARGE: Adulteration (shipment of November 3, 1941), Section 501 (c), the purity of the article fell below that which it purported and was represented to possess. It purported and was represented to be sterile by reason of the fact that it was recommended in the labeling for injection into the cervix and pregnant uterus under conditions of the strictest asepsis, whereas it was not sterile but was contaminated with viable pathogenic micro-organisms.

Misbranding (same shipment), Section 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling; and, Section 502 (a), the labeling was false and misleading since it represented and suggested that the article, when used by or on the prescription of a physician, was a safe and appropriate medicament for use in effecting abortion, whereas, when used by or on the prescription of a physician, or otherwise, it was not a safe and appropriate medicament for use in effecting abortion, but was unsafe and dangerous, and capable of producing serious and even fatal consequences; and the label statements, "The placenta is usually expelled a few minutes after the fetus," "Severe hemorrhages are very rarely observed after the use of Interferin,"

and "the Interferin method is positively superior to dilation and curettage in cases of gravidity from two and a half to six months," were false and misleading since, in cases of abortion induced by the use of the article, the placenta would not usually be expelled a few minutes after the fetus, severe hemorrhages would not be rarely observed after the use of the article, but would frequently occur after such use, and the results obtained by the use of the article in cases of gravidity from 2½ to 6 months would not be superior to those obtained by dilation and curettage.

Misbranding (shipment of March 19, 1942), Section 502 (a), the labeling statements, "Caution: For use by Licensed Physician only. * * * Indications Amenorrhea, Dysmenorrhea, Endocervicitis, Endometritis, Spontaneous, Incomplete, Threatened Abortion," were false and misleading since they represented and suggested that the article, when used by a licensed physician, was a safe and appropriate medicament for use in the treatment of spontaneous, incomplete, and threatened abortion, and that it was a safe and appropriate treatment for amenorrhea, dysmenorrhea, endocervicitis, and endometritis. The article, whether used by a licensed physician or otherwise, was not a safe and appropriate medicament for the treatment of such conditions, but was unsafe and dangerous, and capable of producing serious and even fatal consequences.

DISPOSITION: June 21, 1945. A plea of nolo contendere having been entered by the defendant, the court imposed a sentence of 1 year in jail, to run concurrently with the sentence imposed in the case reported in notices of judgment on drugs and devices, No. 1558.

1553. Misbranding of Stanley's Stomach Powder, Prescription 1-NN-1 Nerve Tablets, Prescription 1-RR-7, External No. 1, Prescription 1-H-7, and Prescription Medicine 1-B-7. U. S. v. Sophia Strboya Sikoparija (Stanley's Drug Store). Plea of not guilty. Tried to the jury; verdict of guilty. Sentence of 57 days in jail. (F. D. C. No. 11379. Sample Nos. 14838-F, 14839-F, 15010-F, 15011-F, 38339-F, 38340-F.)

INFORMATION FILED: May 8, 1944, Eastern District of Texas, against Sophia Strboya Sikoparija, trading as Stanley's Drug Store, Orange, Tex.

ALLEGED SHIPMENT: Between the approximate dates of January 21 and February 20, 1943, from the State of Texas into the States of Wisconsin and California.

PRODUCT: Analyses disclosed that the *Stanley's Stomach Powder* consisted essentially of sodium bicarbonate and Rochelle salt, flavored with anise oil; that the *Prescription 1-NN-1 Nerve Tablets*, the *Prescription 1-RR-7*, and the *Prescription Medicine 1-B-7* contained ½ grain of phenobarbital per tablet; that the *External No. 1* consisted essentially of basic aluminum acetate and sodium acetate; and that the *Prescription 1-H-7* consisted essentially of extracts of plant drugs, including a laxative drug such as senna, sugar, alcohol, and water.

NATURE OF CHARGE: *Stomach Powder*, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be beneficial in the treatment of stomach disorders; that it would be efficacious in the cure, mitigation, treatment, or prevention of stomach pain due to gas, nausea, and heaviness after meals; and that it would be efficacious to correct indigestion, strengthen the digestive organs, and soothe and heal stomach tissues, whereas it would not be efficacious for such purposes; Section 502 (b) (2), the label bore no statement of the quantity of the contents; and, Section 502 (e) (2), the label did not bear the common or usual names of the active ingredients of the article.

Prescription 1-NN-1 Nerve Tablets, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of nervousness, restlessness, sleeplessness, worry or excitement, depressed spirits, and nervous headaches, whereas the article would not be efficacious for such purposes; Section 502 (d), the article contained phenobarbital, a derivative of the narcotic or hypnotic substance barbituric acid, which derivative has been found to be and by regulations designated as habit forming, and its label failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502 (j), the article consisted of tablets, each containing approximately ½ grain of phenobarbital, and it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling, "Direction: Adults: Take 1 Tablet three times a